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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,865	02/07/2005	Hideko Kosaka	10921.0278USWO	1872
52835 7590 05/06/2010 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902				
EXAMINER				
GERIDO, DWAN A				
ART UNIT		PAPER NUMBER		
1797				
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05/06/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/523,865

**Applicant(s)**

KOSAKA, HIDEKO

**Examiner**

Dwan A. Gerido, Ph.D.

**Art Unit**

1797

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 5, 7, 8, 12, 13 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7, 8, 12, 13 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 5, 8, 12, 13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proffit et al., (US 2005/0106748).
4. Regarding claims 1, 8, and 13, Proffit et al., teach a method (examples 5 and 6), indicator (paragraph 0038), and test piece (paragraph 0027) for assaying albumin (paragraphs 0092, 0097) in a urine sample (paragraphs 0050, 0101). Proffit et al., do not explicitly teach measuring albumin with the claimed compounds; however, Proffit et al., do teach phloxine B which is identical to compounds (1)-1, (2)-1, and (3)-1 as a suitable indicator for the assay (paragraph 0038). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the teachings of Proffit et al., wherein phloxine B is used as an indicator determining albumin concentration in a urine sample as taught by Proffit et al.

5. Regarding claims 5, 12, and 17, Proffit et al., teach an indicator (phloxine B, paragraph 0038) identical to that of the instant claims, thus the limitations of color at a particular pH and in the presence of protein are being read as inherent features of the claimed compound.
6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Proffit et al., (US 2005/0106748) in view of Lau (EP 0,361,244).
7. Regarding claim 7, Proffit et al., do not teach measuring an albumin concentration ranging from 10-20mg/dL.

Lau teaches a method of assaying urine albumin wherein the normal concentration of albumin ranges from 10-20 mg/dL (page 7 lines 48-54). Lau further teaches that protein concentrations below 10 mg/dL and above 20 mg/dL are indicative of a protein deficiency and/or disease states (page 7 lines 48-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Proffit et al., in view of Lau to measure albumin in the range of 10-20 mg/dL in order to determine whether a subject exhibits a normal albumin concentration in urine.

8. Claims 18 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Proffit et al., (US 2005/0106748) in view of Albarella et al., (US 5,424,215).
9. Regarding claims 18 and 19, Proffit et al., do not teach a test piece comprising a sensitizer wherein the sensitizer is polyethylene glycol or polypropylene glycol.

Albarella et al., teach an assay for determination of albumin in a urine sample (column 1 lines 19-24) wherein a test strip contains polypropylene glycol as a sensitizer (column 2 lines 32-37, column 4 lines 1-27, table 1). Albarella et al., teach that it is advantageous to utilize a polycarbonate sensitizer as a means of lowering initial reactivity of a reagent paper, and for

decreasing false positive readings for protein concentration (column 1 lines 45-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Proffit et al., in view of Albarella et al., to utilize polypropylene glycol as a sensitizer in order to reduce reactivity of a reagent paper, and to decrease false positives as taught by Albarella et al.

***Response to Arguments***

10. In response to the after final amendment filed on April 20, 2010, the examiner has chosen to reopen prosecution of claims 1, 5, 8, 12, 13, and 17. Claims 1, 8, and 13 are now rejected under 35 U.S.C. 103(a) as being unpatentable over Proffit et al., (US 2005/0106748). Reference to Proffit et al., teach a method, indicator, and test piece for assaying albumin in a urine sample wherein phloxine B is listed as a compound suitable for assaying albumin. The examiner notes that phloxine B is identical in structure to compounds (1)-1, (2)-1, and (3)-1 of the instant claims, and takes the position that one of ordinary skill in the art would have found it obvious to utilize the claimed compound to determine albumin concentration in a urine sample in the manner suggested in reference to Proffit et al.

Claims 18 and 19 are now rejected as being unpatentable over Proffit et al., in view of Albarella et al. Albarella et al., teach an assay for determining albumin concentration in a urine sample comprising a test strip wherein the test strip contains a polycarbonate compound with polypropylene glycol being the preferred compound. Albarella et al., teach that addition of a polycarbonate compound provides the advantage of reducing initial reactivity of the reagent paper, and decreasing false positive results. Therefore, it is the examiners position that reference to Albarella et al., provides sufficient motivation that would have lead one of ordinary skill in the

art to arrive at the instant invention by combining the teachings of Proffit et al., and Albarella et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAG

/ROBERT J. HILL, JR/  
Primary Examiner, Art Unit 1797